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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,961	10/12/2001	Keith L. Black	67789-512	3007

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EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/976,961	BLACK ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 7-11, 17, 19-20, 25-33 and 38-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1 and 7* is/are allowed.

6)☒ Claim(s) *8-11,17,19,20,25-30,33 and 38-43* is/are rejected.

7)☒ Claim(s) *31,32,44 and 45* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Black et al.

Response to the Amendment

The Amendment filed on 01/24/2006 in response to the previous Final Office Action (08/11/2005) is acknowledged and has been entered. The finality of the previous Office Action has been withdrawn upon reconsideration.

Claims 1, 7-11, 17, 19-20, 25-33 and 38-45 are currently pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

All rejections and/or objections are withdrawn in view of applicant's amendments and arguments there to.

New Objections/Rejections necessitated upon reconsideration:

Claim Objections

Claim 19 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case, the recitation of malignant tumors which are not characterized as being a gliomal cell or astrocytoma cell such as meningioma, sarcoma, melanoma, lymphoma or carcinoma as required in independent claim 17, does not appear to further limit the independent claim.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 8-11, 17, 19-20, 25-26, 28-30, 33, 38-39 and 41-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Bamdad et al. (US 2003/0036199, 2003, priority to 5/7/2001).

Bamdad et al (US 2003/0036199, 2003) teach a method of treating a subject having cancer characterized by aberrant expression of MUC1, comprising administering to the subject NS1619 in an amount effective to reduce tumor growth (page 36, 1st column, claim 143 of Bamdad et al.). Specifically, the publication teaches that NS1619 is specific for the MGFR portion of the MUC1 receptor; and further, that it is selective for the malignant cell which express the MGFR portion of MUC1 receptor as compared to nonmalignant cells (page 4, 1st column, paragraph 0051 and page 11, 1st column, paragraph 0113). With regards to the cancer, Bamdad et al. teach that cancer includes, but is not limited to, brain cancers such as glioblastoma and medulloblastoma, liver cancer, breast cancer, prostate cancer, lung cancer, neuroblastoma, sarcoma, melanoma, lymphoma and carcinoma (page 6, 2nd column, paragraph 0084). With regards to the subject, the publication teaches that the subject includes not only humans, but also, non-human primates, cows, horses, pigs, sheep, goats, dogs or cats (page 7, 2nd column, paragraph 0089). With regards to the route of administration, the publication teaches (page 18, 1st column, paragraph 0171) that the route of administration will vary depending on the type of cancer and/ or dosage, but includes single dose direct injection and parental routes of administration such as intravenous or infusion. With regards to the dose, the publication teaches that NY1619 is administered to the subject in an amount from about 1-25 micrograms/kg body mass (page 17, 1st column, paragraph 0162). Although Bamdad et al. does not specifically teach that NY1619 is the calcium-activated potassium channel activator 1,3-dihydro-1-[2-hydroxy-5-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-2H-benzimidazole-2-one, the claimed calcium-activated potassium channel activator appears to be the same as the prior art because the specification teaches (page 10, lines 16-17) that 1,3-dihydro-1-[2-hydroxy-5-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-2H-benzimidazole-2-one is also referred to as NY1619. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989). Moreover, while Bamdad *et al.* do not

explicitly teach that the administration of NY1619 induces apoptosis, the claimed method does not appear to distinguish over the prior art teaching of the same or nearly the same method of inhibiting the growth of a malignant tumor. The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Bamdad et al. (US 2003/0036199, 2003, priority to 5/7/2001) in further view of Yamada et al. (Cancer Research 1987; 47: 2123-2128).

Bamdad et al teach, as applied to claims 8-11, 17, 19-20, 25-26, 28-30, 33, 38-39 and 41-43 above, a method of treating a subject having cancer characterized by aberrant expression of MUC1, comprising administering to the subject NS1619 in an amount effective to reduce tumor growth (page 36, 1st column, claim 143 of Bamdad et al.). With regards to the cancer, Bamdad et al. teach that cancer includes, but is not limited to, brain cancers such as glioblastoma and medulloblastoma, liver cancer, breast cancer, prostate cancer, lung cancer, neuroblastoma, sarcoma, melanoma, lymphoma and carcinoma (page 6, 2nd column, paragraph 0084). With regards to the route of administration, the publication teaches (page 18, 1st column, paragraph 0171) that the route of administration will vary depending on the type of cancer and/ or dosage, but includes single dose direct injection and parental routes of administration such as intravenous or infusion.

Bamdad et al. do not explicitly teach administering NY1619 by intracarotid infusion.

Yamada et al. teach the biodistribution of radiolabeled 1-(4-amino-2methyl-5-pyrimidiny)methyl-3-(2-chloroethyl)-3-nitrosourea hydrochloride in rat brain tumors following intra-arterial or intravenous administration. Specifically, the reference teaches that uptake of the isotope by the tumor was 2-8 times higher after intracarotid infusion than that of intravenous infusion (abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to administer NY1619 as taught by Bamdad et al. by intracarotide infusion in view of the teachings of Yamada et al. that intracarotid infusion increases tumor uptake of radiolabeled agents. One would have been motivated to do so because because Yamada et al. teaches that the uptake of -(4-amino-2methyl-5-pyrimidiny)methyl-3-(2-chloroethyl)-3-nitrosourea hydrochloride in rat brain tumors was 2-8 times higher after intracarotid infusion than that of intravenous infusion (abstract). Thus, one of ordinary skill in the art would have a reasonable expectation that by administering NY1619 to a patient suffering from a brain tumor by intracarotid infusion, one would achieve a method of increasing the tumor uptake of the NY1619 agent as compared to if the agent was administered by intravenous infusion.

Summary

Claims 1 and 7 appear to be in condition for allowance since the prior art does not appear to teach or suggest an in vitro method of inducing apoptosis of malignant cells comprising administering NY1619. The closest prior art, Bamdad et al. (US 2003/0036199, 5/7/2001) discloses a method of treating a subject having cancer characterized by aberrant expression of MUC1, comprising administering to the subject NS 1619 in an amount effective to reduce tumor growth, e.g. inhibits cellular proliferation (page 16, paragraph 0146). The reference does not specifically teach that the compound induces apoptosis in vitro.

Claims 31-32 and 44-45 are objected to as being drawn to a rejected independent claim, but appear to be free of the prior art. The closest prior art, Bamdad et al. (US 2003/0036199, 5/7/2001) discloses a method of treating a subject having cancer characterized by aberrant expression of MUC1, comprising administering to the subject NS 1619 in an amount effective to reduce tumor growth, e.g. inhibits cellular proliferation (page 16, paragraph 0146). The reference does not

specifically teach or suggest administration of the compound to a subject at a dose rate specified in these claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

JEFFREY SIEW
SUPERVISORY PATENT EXAMINE